

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

I. Status of the Claims

Claims 47 and 52 are requested to be amended. Exemplary support for the amendments to claim 47 can be found on page 11 of the specification. Claim 52 is being amended to no longer recite “neural pancreatic thread protein, and pancreatic thread protein.”

Claims 60 is requested to be added. Exemplary support for claim 60 can be found in claim 48.

Because the amendments do not introduce new matter, Applicant respectfully requests entry of the amendments. After entry of the amendments, claims 47-52 and 55-60 will be pending, and claim 52 will be withdrawn. Thus, claims 47-51 and 55-60 will be pending and subject to examination on the merits.

III. Claim Rejections – 35 U.S.C. § 112, First Paragraph

A. Enablement

Claims 47, 49-51, and 55-59 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. According to the Examiner, “the specification, while being enabling for a method of treating a benign tumor, a malignant tumor, hyperplasia, hypertrophy, overgrowth of a tissue and malformation of a tissue in a patient requiring removal or destruction of cells comprising locally administering (e.g., topically, intratumorally) to a mammal in need a therapeutically effective amount of the neural thread protein consisting of SEQ ID NO.10, does not reasonably provide enablement for a method of treating any and all conditions in a patient requiring removal or destruction of cells comprising systemically administering (e.g., intravenously, intra-arterially, intraperitoneally) to a mammal in need a therapeutically effective amount of any and all neural thread protein

(NTP) as well as fragments, variant, derivative, homolog, reverse-D peptide, and enantiomers of NTP.” Office Action at ¶ 5. Applicant respectfully traverses this ground of rejection.

While not acquiescing in the propriety of the rejection, Applicant has amended claim 47 to no longer recite “neural pancreatic thread protein, and pancreatic thread protein.” Thus, the claims cannot be reasonably be construed to encompass “fragments, variant, derivative, homolog, reverse-D peptide, and enantiomers of NTP.”

The specification contains a complete description adequate to enable one of skill in the art to practice the claimed invention without undue experimentation. For example, the specification provides the amino acid sequences for the NTPs recited by the claims. *See e.g.*, Figs. 1-9; pages 9-10. Thus, one of skill in the art can readily obtain the recited peptides. The specification also teaches that exposing tissue to NTP kills the tissue. In fact, the working examples demonstrate that NTP induced acute necrosis regardless of the type of tissues tested or its origin. Because the conditions recited by claim 47 all require removal or destruction of cells, one of skill in the art would expect that the NTP could be used to treat the full scope of these conditions.

The Examiner argues that “absent the evidence that any other NTPs except SEQ ID NO.10, can destroy or remove harmful or unwanted cells, one of skill in the art would not be able to predictably use any of these proteins and functional equivalents thereof for the destruction or removal of harmful or unwanted cells.” Office Action at ¶ 5. However, the specification does provide evidence to support the enablement of the claimed invention. All of the recited sequences, SEQ ID NOS: 2-10, are neural thread proteins (NTPs). Applicants tested one of these NTPs, SEQ ID NO: 10, and demonstrated that it had the desired biological effect. The Examiner argues that these results do not support the enablement of SEQ ID NOS: 2-9, because even single amino acid changes can affect biological activity. However, Applicant SEQ ID NOS: 2-9 are related to SEQ ID NO: 10, because they are all NTPs. NTPs have common biological effects and structural features well-known to those skilled in the art. Accordingly, one of skill in the art would expect SEQ ID NOS: 2-9 to have similar effects to SEQ ID NO: 10.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

B. Written Description

Claims 47, 49-51, and 55-59 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description support. According to the Examiner, “the claims as amended still encompass a method of treating a condition requiring removal or destruction of cells comprising administering fragments, homologs, variants, derivatives, mimetics, reverse-D peptides, and enantiomers of neural pancreatic thread protein, and the instant specification does not provide adequate support for all these modified proteins.” Office Action at ¶ 6.

While not acquiescing in the propriety of the rejection, Applicant has amended claim 47 to no longer recite “neural pancreatic thread protein, and pancreatic thread protein.” Instead, the claims now recite SEQ ID NOS: 2-10. Because the specification provides the amino acid sequences for these polypeptides, the specification provides written description support. Thus, the amendment renders this ground of rejection moot.

IV. Double Patenting

A. Rejection Over U.S. Patent No. 6,924,266

Claims 1-7, 9, 47, and 49-51 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 4-7 of U.S. Patent No. 6,924,266.

Applicant encloses a terminal disclaimer disclaiming the term of any patent issuing from the present application that extends beyond the term of the ‘266 patent. Thus, the terminal disclaimer renders this rejection moot.

B. Rejection Over Co-Pending Applications

Claims 1-7, 9, 47, and 49-51 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over “claims

12-16 and 18 of copending Application No. 10/294,891 and claims 9-13 and 15 of copending Application No. 10/920,313.” Office Action at ¶ 9.

Applicant notes the provisional nature of this rejection and will address the rejection on the merits if it ever matures into a non-provisional rejection.

IV. Claim Rejections – 35 U.S.C. § 102

Claims 47, 49-51, 55, and 59 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,620,922 to Xu *et al.* According to the Examiner, “[b]ecause the term ‘neural pancreatic thread protein’ encompass fragments and functional equivalents of a neural pancreatic thread protein (see above paragraphs 7 and 8), the polypeptide of SEQ ID NO.573 reads on the claimed neural pancreatic thread protein.” Office Action at ¶ 9.

While not acquiescing in the propriety of the rejection, Applicant has amended the claims to no longer recite “neural pancreatic thread protein.” Thus, the amendment renders this ground of objection moot.

CONCLUSION

Applicant believes that the present application is in condition for allowance. Favorable reconsideration is requested, therefore. Also, Examiner Sang is invited to contact the undersigned directly, should any issue warrant further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany the response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extensions of time are needed for timely acceptance of submitted papers, Applicant hereby petitions for such extension under 37 CFR §1.136 and authorizes payment of any such extensions fees from the deposit account.

Respectfully submitted,

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